

1 REMARKS

2 Status of the Claims

3 Claims 1, 2, 4-11, 14, 15, 17-41, 43-45, 48-61, 74, 76-81, and 88-100 are pending in the
4 present application, Claims 13, 42, 46, 47 and 62-73 having been previously canceled, Claims 3, 12,
5 16, 75, and 82-87 having been canceled herein, and Claims 88-100 having been added herein.
6 Claims 1, 2, 4, 7, 9, 11, 14, 15, 55, 56-58, 60, 74 and 79 having been amended to more clearly define
7 the invention.

8 Brief Summary of Telephone Interviews

9 On October 30, 2007, applicant's attorneys (Sabrina MacIntyre, Registration No. 56,912 and
10 Michael King, Registration No. 44,832) conducted a brief telephone interview to discuss the current
11 Office Action with Examiners Musselman and Saadat.

12 Applicant's attorneys asked for clarification with respect to the Examiner's comment on page 8 of
13 the Office Action wherein the Examiner indicated that an amendment with respect to the use of
14 elastomer portions of circuits for many of the sensory techniques of the evaluation circuits wherein
15 the simulated tissue structure itself is the sensory system (with the exception of Nicholls) may be
16 distinguishable over the cited art. Applicant understands Examiner Musselman to have clarified that
17 amendments made to the effect that the simulated physiological structure itself actually includes the
18 evaluation circuit incorporated within the structure, would be distinguishing over the prior art of
19 record. With respect to Nicholls, Examiner Musselman indicated that Nicholls is limited to its one
20 general use. Therefore, applicant understood that amendments to the effect that an evaluation circuit
21 disposed on the physiological structure such as a bone or knee or joint, may be distinguishing.

22 Another issue discussed during the interview was dependent Claim 3 that is directed toward the
23 feature of not using an instrument to perform the simulated procedure. With respect to whether or not
24 Examiner Musselman considers dependent Claim 3 to be distinguishable over the cited art, Examiner
25 Musselman pointed out that we may want to review U.S. Patent No. 6,669,483 (Leight et al.) because it is
26 directed toward sensors embedded in a breast model.

27 Examiner Musselman directed applicant's attorneys to U.S. Patent No. 7,261,566 (Blanck et al.)
28 because it is directed toward a method and system for training medical professionals to perform a nerve
29 block procedure.
30

1 Applicant also understood that a simulated procedure wherein an incision actually opens the
2 evaluation circuit may be distinguishing over the art of record.

3 Applicant's attorneys would like to again thank Examiners Musselman and Saadat for their time
4 and willingness to discuss these issues during the Telephone Interview.

5 On December 10, 2007, Examiner Musselman telephoned applicant's attorney and explained that
6 he was able to briefly review some of the independent claims in the office action response that was
7 informally submitted earlier. With respect to independent Claims 1, 2, 55 and 57 Examiner Musselman
8 indicated that it would be helpful to modify the element of an evaluation circuit "...disposed within the
9 simulated physiological structure" such that the element would distinguish over a prior art sensor being
10 embedded into a simulated physiological structure. Examiner Musselman suggested some language to the
11 effect of "...configured as at least a portion of the simulated physiological structure..." Applicant's
12 attorney agreed to such a modification. With respect to independent Claim 45, the Examiner indicated that
13 the arguments were likely valid over the art. However, the Examiner indicated that he had not yet formed
14 an opinion on the patentability of independent Claims 74 and 79. With respect to independent Claims 88
15 and 89, the Examiner indicated that these claims appeared to distinguish over the art. The Examiner further
16 indicated that independent Claims 91, 94 and 98 did not yet distinguish over Nicholls. With respect to
17 independent Claim 91, the Examiner indicated that Nicholls teaches layers of evaluation circuits that
18 measure position relative to other layers, and that such layers can also determine improperly
19 positioned instruments. With respect to independent Claim 94, the Examiner indicated that Nicholls
20 discloses a target portion (such as the active nerve) and that there is an evaluation circuit disposed
21 between the exterior and the target. The Examiner suggested adding language clarifying that the
22 evaluation circuit was configured to open in response to a correctly performed incision on the
23 simulated physiological structure. With respect to independent Claim 98, the Examiner asserted that
24 Nicholls discloses induction.

25 Applicant's attorneys would like to again thank Examiners Musselman for taking the time to
26 review the proposed amendments and discuss these issues during this second Telephone Interview. The
27 Examiner's efforts have substantially advanced the prosecution of the pending application.
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1 Allowable Subject Matter

2 The Examiner has stated that Claims 53 and 54 are objected to as being dependent upon a
3 rejected base claim, but would be allowable if rewritten in independent form including all of the
4 limitations of the base claim and any intervening claims.

5 Claims Rejected Under 35 U.S.C. § 103(a)

6 Claims 1-3, 7, 10-37, 43-50, 55-74, 76, 78-79, and 82-87 are rejected under
7 35 U.S.C. § 103(a) as being unpatentable over U.S. patent publication 2003/0068606 (Nicholls et al.–
8 hereinafter referred to as “Nicholls”) in view of U.S. Patent 5,853,292 (Eggert et al. – hereinafter
9 referred to as “Eggert”).

10 Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls in view
11 of Eggert and further in view of U.S. Patent 5,967,790 (Strover et al. – hereinafter referred to as
12 “Strover”).

13 Claims 8-9 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls
14 in view of Eggert and further in view of U.S. Patent 5,589,639 (D’Antonio et al. – hereinafter
15 referred to as “D’Antonio”).

16 Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls in view of
17 Eggert and further in view of U.S. Patent 6,857,878 [*sic*] (Pugh).

18 Claims 77 and 80-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls
19 in view of Eggert and further in view of U.S. Patent 6,857,878 [*sic*] (Beach et al. – hereinafter
20 referred to as “Beach”).

21 In the interest of reducing the complexity of the issues for the Examiner to consider in this
22 response, the following discussion focuses on independent Claims 1, 2, 45, 55, 57, and 74. Please note
23 that although the patentability of at least one dependent claim is discussed, the patentability of each
24 remaining dependent claim is not necessarily separately addressed in detail. However, applicant’s
25 decision not to discuss the differences between the cited art and each dependent claim should not be
26 considered as an admission that applicant concurs with the Examiner’s conclusion that these dependent
27 claims are not patentable over the disclosure in the cited references. Similarly, applicant’s decision not
28 to discuss differences between the prior art and every claim element, or every comment made by the
29 Examiner, should not be considered as an admission that applicant concurs with the Examiner’s
30 interpretation and assertions regarding those claims. Indeed, applicant believes that all of the dependent

1 claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection
2 of each dependent claim is not required, since dependent claims are patentable for at least the same
3 reasons as the independent claims from which the dependent claims ultimately depend.

4 Patentability of Independent Claim 1

5 Claim 1 distinguishes over the cited art because the cited art does not teach or suggest an
6 evaluation circuit including a **conductive path** that is opened when a simulated physiological
7 structure is manipulated.

8 The Examiner has indicated that although Nicholls fails to teach that the circuit is opened,
9 Eggert discloses that concept. The Examiner explains that it would have been obvious to one of
10 ordinary skill in the art at the time of the invention to utilize evaluation circuits that use various sensor
11 types and concepts as taught by Eggert with the conductive elastomer pathways in the system of
12 Nicholls, in order to provide additional sensor types and training uses for the system. In support of this
13 assertion, the Examiner references column 5, lines 38-46 of Eggert (reproduced below):

14 The ET tube 18b is used to confirm proper placement in the tracheal airway of the
15 manikin 28. A sensor 20b, comprising an optical sensor of conventional design, is
16 mounted in the wall of the trachea of the manikin 28 and connected by a line 60 to the
17 IV/ET port 40. The ET tube 18b is fitted with a piece of reflective tape 18b' fitted near
18 the distal, or lower, end of the tube. Correct placement of the ET tube 18b in the
trachea is confirmed *when the distal reflective tip of the ET tube interrupts the beam of
the optical sensor 20b.* (Emphasis added, Eggert, column 5, lines 38-46.)

19 Applicant respectfully disagrees with the Examiner's conclusion that Eggert discloses any
20 action that opens a *conductive pathway* in an evaluation circuit. As indicated in the italicized portion of
21 the above excerpt, Eggert is clearly teaching that a beam of light is interrupted. In contrast, applicant
22 recites that a *conductive path is opened*. Applicants respectfully submit that causing a **beam of light** to
23 be interrupted is *NOT* equivalent to causing a **conductive path** to be opened. In other words,
24 interrupting a light beam is not equivalent to breaking an electrical connection.

25 Accordingly, the rejection of independent Claim 1 under 35 U.S.C. § 103(a) should be
26 withdrawn, because the cited art does not teach or suggest all of the recitation of Claim 1.

27 In order to further clarify the subject matter applicant has claimed, applicant has amended
28 Claim 1 to make it clear that the portion of the evaluation circuit that includes the conductive path that
29 is opened (i.e., that is "broken") is disposed within the simulated physiological structure.
30

1 Patentability of Independent Claim 2

2 Claim 2 has been amended to recite a simulator comprising a simulated physiological structure
3 and:

4 (b) *an evaluation circuit including a conductive elastomer, the conductive*
5 *elastomer enhancing the realism of the ~~simulator~~ simulated physiological structure, the conductive*
6 *elastomer being configured as a portion of the simulated physiological structure, said evaluation*
7 *circuit being configured to provide [[a]] an electrical signal relating to a simulated procedure being*
8 *performed on the simulated physiological structure, the electrical signal originating from the portion*
9 *of the simulated physiological structure including the conductive elastomer without requiring:*

10 (i) *an electrical current to be provided by an instrument placed in contact*
11 *with the evaluation circuit during the simulated procedure or*

12 (ii) *the use of an electrically conductive instrument to electrically couple*
13 *portions of the evaluation circuit together.*

14 The Examiner has noted that Nicholls discloses a simulator including a conductive elastomer
15 where an electrical current is provided to an evaluation circuit by an instrument, and that Eggert
16 discloses a conductive instrument that electrically couples different portions of an evaluation circuit
17 together (where Eggert's circuit does not include a conductive elastomer).

18 Even if combined as suggested by the Examiner, a combination of Eggert and Nicholls does not
19 achieve the recited structure, because of the language added in subparagraphs (i) and (ii).

20 The Examiner has also noted the existence of a reference that discloses a breast model (U.S.
21 Patent No. 6,669,483; referred to hereafter as Leight), where no instrument is required. Significantly,
22 the language in Claim 2 reciting *the electrical signal originating from the portion of the simulated*
23 *physiological structure including the conductive elastomer* distinguishes over Leight, because the
24 structure disclosed by Leight includes a plurality of displacement surfaces within a breast model, where
25 the displacement surfaces are coupled to external sensors using string that extends from within the
26 breast to the external sensors. An electrical signal is generated by the sensors, but that signal is
27 generated *outside* of the simulated physiological structure.

28 The cited art simply does not teach or suggest a simulated physiological structure including a
29 conductive elastomer based evaluation circuit disposed in the simulated physiological structure, where
30 an electrical signal is originated from within the simulated physiological structure during a simulation,

1 without requiring the use of an instrument that provides an electrical current, or a conductive instrument
2 that electrically couples together two portions of the evaluation circuit. To achieve an equivalent
3 structure, it would appear that the prior art references would need to be modified based on an
4 impermissible application of hindsight.

5 Significantly, the simulator defined in Claim 2 as amended reads on several different
6 embodiments disclosed by applicant. For example, the language encompasses simulated physiological
7 structures in which a sensor (such as a pressure sensor) has been incorporated, as well as simulated
8 physiological structures that include an energized evaluation circuit, where the energized evaluation
9 circuit is configured to open when the simulated physiological structure is manipulated (for example, a
10 simulated joint in which the evaluation circuit is energized (or not) when the joint is properly seated in
11 a socket, with the evaluation circuit not being energized when the joint is not properly seated in the
12 socket).

13 Accordingly, the rejection of independent Claim 2 under 35 U.S.C. § 103(a) should be
14 withdrawn. Because dependent claims include all of the elements of the independent claim from which
15 the dependent claims ultimately depend, dependent Claims 4-11, 14-15, 17-41, and 43-44 are
16 patentable for at least the reasons discussed above in regard to independent Claim 2, and the rejection
17 of dependent Claims 4-11, 14-15, 17-41, and 43-44 under 35 U.S.C. § 103(a) should be withdrawn.

18 Patentability of Independent Claim 45

19 Claim 45 distinguishes over the cited art because the cited art does not teach a simulated
20 physiological structure including first and second conductive segments that are *placed in physical*
21 *contact with each other* during a simulated procedure.

22 The Examiner has asserted that Nicholls discloses a medical simulator including a conductive
23 elastomer based evaluation circuit, and that Eggert discloses a medical simulator that includes
24 conductive segments that are electrically coupled together during a simulated procedure by a
25 conductive instrument. The Examiner argued that it would have been obvious to modify the conductive
26 elastomer evaluation circuit disclosed by Nicholls to function as taught by Eggert, in order to provide
27 versatility with regard to sensory and data acquisition options and expand the training uses for the
28 device.

29 Applicant respectfully disagrees. Significantly, using an electrically conductive instrument to
30 *electrically couple* two conductive segments together is NOT equivalent to *physically coupling* the

1 segments together. It may be helpful to note applicant's FIGURE 11B shows segments being
2 physically coupled together

3 Accordingly, the rejection of independent Claim 45 under 35 U.S.C. § 103(a) should be
4 withdrawn, because the cited art does not teach or suggest all of the claim recitation of Claim 45.
5 Because dependent claims include all of the elements of the independent claim from which the
6 dependent claims ultimately depend, dependent Claims 48-54 are patentable for at least the reasons
7 discussed above in regard to independent Claim 45, and the rejection of dependent Claims 48-54 under
8 35 U.S.C. § 103(a) should be withdrawn.

9 Patentability of Independent Claim 55

10 Claim 55 has been amended to include language similar to that employed in Claim 2. As
11 amended, Claim 55 recites a model including an evaluation circuit and a simulated physiological
12 structure, where:

13 at least a segment of the evaluation circuit including the conductive elastomer being configured
14 as a portion of the simulated physiological structure, wherein the evaluation circuit is configured to
15 provide data via an electrical signal originating from the portion of the simulated physiological
16 structure in response to at least one of the following conditions:

17 Significantly, the language in Claim 55 requires that the electrical signal from the evaluation
18 circuit providing feedback about a simulation originate from within the simulated physiological
19 structure. As noted above, this language has been specifically employed to distinguish Leight, because
20 the structure disclosed by Leight physically couples a simulated physiological structure to externally
21 disposed sensors, and the electrical signals are originated at the external sensors.

22 The following conditions referred to in Claim 55 each distinguish over the structures of
23 Nicholls, Eggert, and Leight. Nicholls discloses an evaluation circuit including a conductive elastomer,
24 where the circuit is configured to be energized by a probe supplying an electric current. Eggert
25 discloses an evaluation circuit (not including a conductive elastomer), where the circuit is configured to
26 be energized by an external source, and a conductive probe electrically couples adjacent portions of the
27 circuit together, to "close" the circuit. Leight discloses an evaluation circuit that is external of a
28 simulated physiological structure, but mechanically coupled to the physiological structure to detect
29 physical motion of the simulated physiological structure.

1 With respect to each of subparagraph (a)-(g), note the electrical signal originates in the
2 simulated physiological structure (which distinguishes over Leight) without using an electrically
3 conductive instrument that introduces an electrical current in the evaluation circuit (which
4 distinguishes over Nicholls), or an electrically conductive instrument that provides the conductive
5 path between different portions of the evaluation circuit (which distinguishes over Eggert).
6 Applicant's specification provides other mechanisms enabling an electrical signal to originate from a
7 portion of an evaluation circuit disposed within a simulated physiological structure, including
8 physically coupling two portions of an evaluation circuit together (such as by removing a
9 nonconductive portion and suturing the conduct of portions together, or applying pressure to close a
10 gap between adjacent portions of the evaluation circuit), and by using evaluation circuits that can
11 detect changes in capacitance and ambient electrical fields. It would appear that the modifications
12 required of the cited art to achieve an equivalent structure would impermissibly rely on hindsight.

13 For subparagraph (a), the following embodiments disclosed by applicant appear to distinguish
14 over the cited art: FIGURES 10A (where a joint is placed back in the socket or where adjacent ends
15 are sutured together), 10B (where a complete circuit is broken by cutting a portion of the simulated
16 physiological structure with a scalpel), 11A (where a probe/finger touches the simulated
17 physiological structure and the signal originates from within the simulated physiological structure),
18 11B (where a gap exists in the evaluation circuit in the simulated physiological structure, and that gap
19 is closed by manipulating the simulated physiological structure), 11C/11D (where the tool is used to
20 close a radio sensitive switch incorporated into the simulated physiological structure), and 11E
21 (where the tool changes the position of a capacitance sensitive switch incorporated into a simulated
22 physiological structure).

23 For subparagraph (b), the following embodiments disclosed by applicant appear to distinguish
24 over the cited art: FIGURES 11A (where a probe/finger touches the simulated physiological structure
25 and the signal originates from within the simulated physiological structure), and 11B (where a gap
26 exists in the evaluation circuit in the simulated physiological structure, and that gap is closed by
27 manipulating the simulated physiological structure).

28 For subparagraph (c), the following embodiments disclosed by applicant appear to distinguish
29 over the cited art: FIGURES 11A (where a probe/finger touches the simulated physiological structure
30 and the signal originates from within the simulated physiological structure), 11B (where a gap exists

1 in the evaluation circuit in the simulated physiological structure, and that gap is closed by
2 manipulating the simulated physiological structure), 11C/11D (where the tool is used to close a radio
3 sensitive switch incorporated into the simulated physiological structure), and 11E (where the tool
4 changes the position of a capacitance sensitive switch incorporated into a simulated physiological
5 structure).

6 For subparagraph (d), the following embodiments disclosed by applicant appear to distinguish
7 over the cited art: FIGURES 10A (where a joint is placed back in the socket or where adjacent ends
8 are sutured together), 11A (where a probe/finger touches the simulated physiological structure and
9 the signal originates from within the simulated physiological structure), 11B (where a gap exists in
10 the evaluation circuit in the simulated physiological structure, and that gap is closed by manipulating
11 the simulated physiological structure), 11C/11D (where the tool is used to close a radio sensitive
12 switch incorporated into the simulated physiological structure), and 11E (where the tool changes the
13 position of a capacitance sensitive switch incorporated into a simulated physiological structure).

14 For subparagraph (e), the following embodiment disclosed by applicant appears to distinguish
15 over the cited art: FIGURE 10B (where a complete circuit is broken by cutting a portion of the
16 simulated physiological structure with a scalpel).

17 For subparagraph (f), the following embodiment disclosed by applicant appears to distinguish
18 over the cited art (see the first paragraph of page 15): *The use of appropriate sensors in a conductive*
19 *elastomer-based evaluation circuit will enable changes in physical properties of the model to be*
20 *evaluated. For example, some medical procedures involve the application of chemicals (i.e., drugs),*
21 *heat, cold, and/or electromagnetic radiation to tissue or other physiological structures. Appropriate*
22 *sensors can be incorporated into conductive elastomeric-based evaluation circuits so that feedback*
23 *relating to the physical property change can be gathered.*

24 For subparagraph (g), the following embodiments disclosed by applicant appear to distinguish
25 over the cited art: FIGURES 11C/11D (where the tool is used to close a radio sensitive switch
26 incorporated into the simulated physiological structure), and 11E (where the tool changes the position
27 of a capacitance sensitive switch incorporated into a simulated physiological structure).

28 Accordingly, the rejection of independent Claim 55 under 35 U.S.C. § 103(a) should be
29 withdrawn. Because dependent claims include all of the elements of the independent claim from which
30 the dependent claims ultimately depend, dependent Claim 56 is patentable for at least the reasons

discussed above in regard to independent Claim 55, and the rejection of dependent Claim 56 under 35 U.S.C. § 103(a) should be withdrawn.

Patentability of Independent Claim 57

an evaluation circuit comprising a conductive elastomer, at least some of the conductive elastomer being configured as a portion of the simulated physiological structure

As amended, Claim 57 emphasizes that 1) *at least some of the conductive elastomer (comprising the evaluation circuit) is configured as a portion of the simulated physiological structure*, 2) an electrical signal originates from the evaluation circuit within the simulated physiological structure, and 3) the evaluation circuit is configured to produce the electrical signal without requiring the use of *an electrically conductive instrument configured to introduce an electrical current into the evaluation circuit or provide a conductive path between different portions of the evaluation circuit*.

As discussed in detail above, such language distinguishes over Leight, Nicholls and Eggert; and the modifications required of the cited art to achieve an equivalent would appear to impermissibly rely on hindsight.

Accordingly, the rejection of independent Claim 57 under 35 U.S.C. § 103(a) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 58-61 are patentable for at least the reasons discussed above in regard to independent Claim 57, and the rejection of dependent Claims 58-61 under 35 U.S.C. § 103(a) should be withdrawn.

Patentability of Independent Claim 74

Claim 74 has been amended to recite the step of selectively outputting the feedback from the evaluation circuit to different locations (such as to the student, the instructor, or storage).

The Examiner has correctly noted that the prior art discloses evaluation circuits, however, the prior art does not appear to teach or suggest the step of determining to which one of a plurality of locations the feedback will be output.

Significantly, Nicholls does not teach or suggest that the evaluation circuit can be *selectively configured* such that a user is enabled to whom the indication is going to be provided. The indication may be provided to the person performing the procedure, to another party or to an electronic storage location. Support for this amendment is found in the specification on page 57, lines 25-page 58, line 2. Such a step appears to patentably distinguish over the cited art.

1 Accordingly, the rejection of independent Claim 74 under 35 U.S.C. § 103(a) should be
2 withdrawn. Because dependent claims include all of the elements of the independent claim from which
3 the dependent claims ultimately depend, dependent Claims 77-78 are patentable for at least the reasons
4 discussed above in regard to independent Claim 74, and the rejection of dependent Claims 77-78 under
5 35 U.S.C. § 103(a) should be withdrawn.

6 Patentability of Independent Claim 79

7 Claim 79 has been amended to recite that the simulated physiological structure includes a
8 conductive elastomer based evaluation circuit, and that the simulated physiological structure is either a
9 bone or a joint. Such embodiments are clearly disclosed in applicant's disclosure, and the cited art does
10 not appear to teach or suggest incorporating a conductive elastomer in either type of simulated
11 physiological structure. Although the Examiner notes that the prior art does teach surgical training
12 devices that include joints and bones, there simply is no teaching in the prior art about how to
13 incorporate a conductive elastomer into such a joint or bone, or how such a structure would facilitate
14 medical training. Modifying the cited art to achieve an equivalent structure would appear to
15 impermissibly rely upon hindsight.

16 Accordingly, the rejection of independent Claim 79 under 35 U.S.C. § 103(a) should be
17 withdrawn. Because dependent claims include all of the elements of the independent claim from which
18 the dependent claims ultimately depend, dependent Claims 80-81 are patentable for at least the reasons
19 discussed above in regard to independent Claim 79, and the rejection of dependent Claims 80-81 under
20 35 U.S.C. § 103(a) should be withdrawn. Claims 81 through 87 have been canceled herein.

21 Patentability of Independent Claim 88

22 New Claim 88 represents rewriting Claim 53 (to which the Examiner objected) in independent
23 form. Claim 88 is patentable for at least the same reasons as Claim 53.

24 Patentability of Independent Claim 89

25 New Claim 89 represents rewriting Claim 54 (to which the Examiner objected) in independent
26 form. Claim 89 is patentable for at least the same reasons as Claim 54.

27 Patentability of Independent Claim 90

28 New independent Claim 90 recites the method of evaluating the performance of a trainee
29 during a simulated medical procedure by monitoring a conductive elastomer based evaluation circuit.
30 Significantly, the conductive elastomer based evaluation circuit that is monitored is in a portion of a

1 simulated physiological structure that should not be accessed during a simulated procedure. For
2 example, referring to applicant's FIGURE 15, note that veins 392 might be improperly damaged
3 when attempting to access organ 406. The cited art does teach using simulators with evaluation
4 circuits to determine if a trainee has properly performed the procedure by placing the evaluation
5 circuits in locations that will be visited during the proper performance of the simulated medical
6 procedure. However, it does not appear that the cited art teaches or suggests positioning evaluation
7 circuits at critical locations (such as veins) that must not be damaged during the performance of a
8 simulated medical procedure, in order to verify that such structures remain undamaged during a
9 simulated medical procedure. Note that if the evaluation circuit was incorporated only into
10 organ 406, then that evaluation circuit would note that organ 406 was properly reached during a
11 simulated medical procedure, without also providing an indication that veins 392 were undesirably
12 damaged in attempting to access organ 406. Such a medical simulator would improperly rank such a
13 simulated medical procedure as being successful. Support for this claim is found in the specification
14 on page 52, line 16-page 53, line 7.

15 Patentability of Independent Claim 91

16 New independent Claim 91 is generally based on new Claim 90, defining a simulator
17 including two conductive elastomer based evaluation circuits inside of a simulated physiological
18 structure, where one of the evaluation circuits provides an indication that an instrument used in a
19 simulated medical procedure *is* properly positioned during the simulated procedure, and the second
20 evaluation circuit provides an indication that an instrument used in a simulated medical procedure *is*
21 *not* properly positioned during the simulated procedure.

22 Significantly, the first and second evaluation circuit define two dimensional regions, each of
23 which are parallel to an outer surface of the simulated physiological structure. Such a configuration
24 is shown in applicant's FIGURES 15, 16, and 17A. Even if Nicholls evaluation circuits are
25 considered to be two dimensional, they simply are not parallel to the outer surface of the torso/arm in
26 Nicholls' model.

27 Patentability of Dependent Claim 92, 93 and 94

28 New Claims 92 and 93 recite a simulator based on the embodiments of FIGURES 14A and
29 14B, where different evaluation circuits (each comprising the conduct of elastomer) are incorporated
30 into a simulated physiological structure, and are coupled to differently colored lights, enabling a trainee

1 to observe the lights to determine whether or not an instrument being used in a simulated procedure is
2 properly positioned. The cited art does not teach or suggest an equivalent simulator.

3 New Claim 93 depends from Claim 92, and further recites evaluation circuits configured to
4 indicate that the tool is positioned improperly, while providing the trainee contextual information
5 regarding whether the tool is positioned relatively close to a target area, or relatively far away from a
6 target area. The cited art does not teach or suggest an equivalent simulator.

7 New Claim 94 depends from Claim 91, and further recites a third evaluation circuit, and that
8 the first, second, and third evaluation circuits achieve a bulls eye configuration (as shown in
9 applicant's FIGURES 16 and 17A). The cited art does not teach or suggest an equivalent simulator.

10 Patentability of Independent Claim 95

11 New independent Claim 95 is generally based on new Claim 90, defining a simulator
12 including two conductive elastomer based evaluation circuits inside of a simulated physiological
13 structure, where both of the evaluation circuits provides an indication that an instrument used in a
14 simulated medical procedure *is* properly positioned during the simulated procedure.

15 Significantly, the first and second evaluation circuit define two dimensional regions, each of
16 which are spaced apart from one another and parallel to one another. Such a configuration is shown
17 in applicant's FIGURES 15 and 17B. Even if Nicholls' evaluation circuits are considered to be two
18 dimensional, they simply are not parallel to each other and spaced apart (instead, they are concentric).

19 Patentability of Independent Claim 96

20 New independent Claim 96 is directed toward an incision being made in at least a portion of
21 the simulated physiological structure, such that said evaluation circuit is configured to provide a
22 signal indicating that the conductive path through the evaluation circuit has been opened. For
23 example, in applicant's FIGURE 15 an incision must be made through a simulated tissue structure in
24 order to reach simulated organ 406. A plurality of elastomer based evaluation circuits 394, 396, 398,
25 400, 402, and 404 are positioned to determine that organ 406 is successfully accessed during a
26 simulated medical procedure. The cited art does not teach or suggest using conductive elastomer
27 based evaluation circuits in this manner.

28 Patentability of Independent Claim 97

29 New independent Claim 97 is directed toward a simulator that includes a conductive
30 elastomer based evaluation circuit inside of a simulated physiological structure, where the evaluation

1 circuit includes a gap separating a first conductive portion from a second conductive portion, where
2 the gap is configured to be closed during the proper performance of a simulated medical procedure.
3 The cited art does not teach or suggest such a configuration (see applicant's FIGURE 10B).

4 Patentability of Independent Claim 98

5 New independent Claim 98 is directed toward a simulator that includes a conductive
6 elastomer based evaluation circuit inside of a simulated physiological structure, wherein the simulator
7 further comprises a selector switch enabling the output from the evaluation circuit to be hidden from
8 the trainee (i.e., sent to a proctor) or provided to the trainee, enabling the same unit to be used for
9 practice and blind testing (i.e., testing w/o providing feedback during the test to the trainee). The
10 cited art does not teach or suggest such a configuration (see applicant's FIGURE 16).

11 Patentability of Independent Claim 99

12 New independent Claim 99 is directed toward a simulator that includes a conductive
13 elastomer based evaluation circuit inside of a simulated physiological structure, wherein the
14 simulated physiological structure further comprises either a radiosensitive switch or a capacitance
15 based switch configured to be actuated when the simulated procedure is properly performed. While
16 the Examiner has noted that such switches are known, the cited art simply does not teach or suggest
17 incorporating such a switch into a conductive elastomer based evaluation circuit *that is part of a*
18 *simulated physiological structure*. The modifications to the cited art required to achieve an
19 equivalent appear to impermissibly rely upon hindsight. Significantly, the reference disclosing such
20 switches (D'Antonio) relates to sports equipment, not medical simulators, and there is no evidence
21 that an artisan of ordinary skill would have felt compelled to use such a switch in a medical
22 simulator.

23 Patentability of Independent Claim 100

24 New independent Claim 100 is directed toward a simulator that includes a conductive
25 elastomer based evaluation circuit inside of a simulated physiological structure, and a tool configured
26 to induce an electrical current in the conductive elastomer based evaluation circuit when the
27 simulated procedure is properly performed, without there being contact between the tool and the
28 circuit. While the Examiner has noted that induction is known, the cited art simply does not teach or
29 suggest using induction to determine if a simulated medical procedure has been properly performed,
30 where current is induced in a conductive elastomer based evaluation circuit that is part of a simulated

1 physiological structure and wherein said induction occurs without said tool being in physical contact
2 with the evaluation circuit. The modifications to the cited art required to achieve an equivalent
3 appear to impermissibly rely upon hindsight (see applicant's FIGURE 22A).

4 Conclusion

5 In view of the amendments and the remarks submitted above, it should be apparent that all of
6 the claims now submitted define patentable subject matter that is neither anticipated nor obvious in
7 view of the prior art cited. Therefore, the Examiner is requested to issue the present patent. If there
8 are any questions that might be addressed by a telephone interview, the Examiner is invited to
9 telephone the undersigned attorney, at the number listed below.

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11 Respectfully submitted,

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14 /mike king/
15 Michael C. King
16 Registration No. 44,832
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